UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,791	12/28/2000	Keiko Neriishi	2016-0166P	6258

2292 7590 07/26/2002

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/749,791	Nariishi, K.	
	Examiner	Art Unit	
	Chakrabarti, A.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. Claims 4-5 have been canceled and new claims 6-7 have been added.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-3 and 6-7 are rejected under 35 U.S.C. 103 (a) over Some et al. (U.S. Patent 6,256,405 B1) (July 3, 2001)in view of Linsley et al. (U.S. Patent 6,271,002 B1) (August 7, 2001) further in view of Ward et al. (U.S. Patent 4,711,955).

Some et al teach a process for detecting a complementary DNA fragment which comprises the steps of:

a) bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a group of DNA, so that the complementary DNA fragments are fixed by hybridization to the area in which the group is fixed (Column 7, lines 18-38);

b) removing unfixed sample DNA fragments from the hybridized DNA (Column 7, lines 38-43).

C) keeping the hybridized DNA in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of DNAs are hybridized, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50);

d) irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28);

e) detecting the stimulated emission photoelectrically to obtain a series of electric signals (Figures 1 and 8 and Column 8, lines 1-23 and 29-52);

f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed (Figure 6 and Column 12, lines 21-67).

Some et al teach a process, in which area on the radiation image storage panel other than the area of stimulable phosphor is covered by a barrier member made of ceramic material (Figures 1 and 8 and Column 8, lines 10-23).

Some et al teach a process, in which the irradiation image storage panel is irradiated with a stimulating light after it is separated from the hybridized DNA (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28).

Some et al further teach a method in which a solid support having at least two defined areas, each area having a group of nucleotide derivatives, specifically DNA fragments which page 8, line 6 of the specification notes are within the definition of "nucleotide derivatives", under conditions such that the DNA fragments in one area differ in sequence from the DNA fragments fixed in another area (column 7, lines 20-24). In particular, Some states "a plurality of DNA fragments containing specific gene information are separated and distributed on a gel support medium (column 7, lines 20-24)", followed by transfer to nitrocellulose (column 7).

While Some et al teach the structure required for DNA microarrays, meeting that limitation, Some et al do not discuss the narrow meaning of microarray as a gridded solid support with bound nucleic acids (which limitation, while currently not in the claims, is shown in figure 1).

Linsley et al teach a process, which comprises a DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a

group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area. (Column 23, line 50 to Column 27, line 24).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area. of Linsley et al. into the DNA image forming method of Some et al. since Linsley et al. state, "One particular useful method of assaying gene expression at the level of transcription employs DNA microarrays (Column 1, lines 53-55)." By employing scientific reasoning, an ordinary artisan would have combined and substituted DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area of Linsley et al. into the DNA image forming method of Some et al. to improve the process for detecting a complementary DNA fragment. An ordinary practitioner would have been motivated to combine and substitute DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area of Linsley et al. into the DNA image forming method of Some et al in order to achieve the express advantages , as noted by Linsley et al., of one particular useful method of assaying gene expression at the level of transcription that employs DNA microarrays.

Some et al in view of Linsley et al. do not teach a process wherein a group of nucleotide derivatives and analogues are fixed on the microarray.

Ward et al teach a process of using a group of nucleotide derivatives and analogues (Abstract and Claims 1-21).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method of using a group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of Some et al. in view of Linsley et al. since Ward et al. state, "Application include detection and localization of polynucleotide sequences in chromosomes, fixed cells, tissue sections, and cell extracts. Specific applications include chromosomal karyotyping, clinical diagnosis of nucleic-acid containing etiological agents, e.g., bacteria, viruses, or fungi, and diagnosis of genetic disorders (Abstract, last two sentences)." Ward et al provide further motivation as Ward et al. state, "Moreover, these nucleotide derivatives are chemically stable and can be expected to have functional shelf-lives of several years or more. Finally, these compounds permit the development of safer, more economical, more rapid, and more reproducible research and diagnostic procedures (Column 3, lines 11-17)". By employing scientific reasoning, an ordinary artisan would have combined and substituted the method of using a group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of Some et al. in view of Linsley et al. to improve the process for detecting a complementary DNA fragment. An ordinary practitioner would have been motivated to combine and substitute the method of using a

group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of Some et al. in view of Linsley et al., in order to achieve the express advantages, as noted by Ward et al., of nucleotide derivatives that are chemically stable and can be expected to have functional shelf-lives of several years or more and which permit the development of safer, more economical, more rapid, and more reproducible research and diagnostic procedures and whose application include detection and localization of polynucleotide sequences in chromosomes, fixed cells, tissue sections, and cell extracts and chromosomal karyotyping, clinical diagnosis of nucleic-acid containing etiological agents, e.g., bacteria, viruses, or fungi, and diagnosis of genetic disorders.

Response to Amendment

4. In response to amendment, rejections under 112 (second paragraph) and 102(e) have been withdrawn. However, rejections under 35U.S.C. 103 (a) have been properly maintained.

Response to Arguments

5. Applicant's arguments filed on June 5, 2002 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant has argued that Linsley et al and Ward et al are completely silent about the characteristic feature of the claimed invention. It has been clearly stated in the last office action what elements are taught by Linsley et al and Ward et al references.

In view of the response to argument, 103(a) rejections are hereby properly maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

July 17, 2002

ETHAN C. W[illegible]NANT
PRIMARY EXAMINER